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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,635	OLSON, BENGT KRISTER4	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-69,73-76,79,82-87 and 90-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-69,73-76,79,82-87 and 90-103* is/are rejected.

7)☒ Claim(s) *65-69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendment filed 05 November 2004 to Office Action mailed 05 May 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

CLAIMS STATUS

2. Claims 92-103 have been added.

3. Claims 70-72, 77-78, 80-81 and 88-89 have been cancelled.

4. Claims 65-69, 73-74, 76, 79, 82-84, 86-87 and 90-91 have been amended.

5. Claims 65-69, 73-76, 79, 82-87 and 90-103 are pending and are examined on Merits

Claims Objection

6. In view of applicant's amendment filed 05 November2004, Claims 65-69 are objected to for the following reasons:

- In Claim 65 at Lines 7-8 each, in between the words "polyphenolic" and "hydrophilic" a --, -- should be inserted.
- Claims 66-69 are objected to because at Line two of each one of the cited Claims, in between the words "polyphenolic" and "hydrophilic" a --, -- should be inserted.

Appropriate correction is required.

Claim Rejections Under 35 U.S.C. §§ 112, 102(b) and 103(a)

7. In response filed 05 November 2004 to Claim ejections under each one of the 35 U.S.C.§§ 112, 102(b) and 103(a) in the Office Action mailed 04 May 2004, applicant argues that applicant has amended claims 65-69, 73-74, 76, 79, 82-84, 86-87 and 90-91 and canceled Claims 70-72, 77-78, 80-81 and 88-89. Therefore, Examiner should withdraw all the rejections made under each of 35 U.S.C. sections 112, 102(b) and 103(a) in Office Action mailed 05 May 20004.

Applicant's arguments filed 05 November 2004 in regard to rejections made in the Office Action mailed 05 May 2004 in regard to Claims 65 t0 69, 71 to 76, 78-91 and newly filed Claims 92-103 dependent directly or indirectly upon Claim65 have been fully and carefully considered but they are not persuasive for the reasons of record in the Office action mailed 05 May 2005 and for the additional reasons discussed below. The rejections under 35 U.S.C. § 112, first paragraph are adhered to for the reasons of record.

35 U.S.C. § 112

First Paragraph Rejections

8. In response to the enablement/scope rejections of Claims 65-69, 71, 73-76 and 78-91 under 35 U.S.C. §112, first paragraph in the Office Action mailed 05 May 2004, applicant argues that applicant has deleted the term "cartilage extract" or "tomato extract" in Claim 65. "Accordingly, the rejection of Claims 66-69, 73, 75-76, 79, 82-83, 85 and 90-91 which directly or indirectly depend from Claim 65 and also do not contain the terms "cartilage extract" or "tomato extract" has been rendered moot".

Applicant s' arguments filed 05 November 2004 in regard to rejections made in the Office Action mailed 05 November 2004 have been fully and carefully considered, but they are not persuasive. The rejections under 35 U.S.C. § 112, first paragraph to Claims 74 and 85-86 are adhered to for the reasons of record and because Claims 74 and 85-86 still recite the word "extract".

9. In view of applicant's amendment filed 05 November 2004, following is a new rejection under 35 U.S.C. §112, first paragraph to Claims 65-69, 71, 73-76 and 78-91 and newly presented Claims 92-103 that are dependent directly or indirectly on Claim 65.

10. Claims 65-69, 73-76 and 79, 82-87, 90-91 and newly presented Claims 92-103 dependent directly or indirectly on Claim 65 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for preparing a "grape seed extract", does not reasonably provide enablement for preparing a "cartilage enzymatic hydrolysate" or "tomato Extract" or "*Acerola* extract" as stated for e.g., in Claims 65, 74 and 85-86. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure, applicant has demonstrated a composition comprising a "Cartilage enzymatic hydrolysate" or "tomato Extract" or "*Acerola* extract" (Specification, Page 5, Lines 10-15. Applicant has not provided any clear guidance regarding the preparation of "Cartilage enzymatic hydrolysate" (e.g., enzyme dosage, enzyme to substrate ratio, duration of reaction, temperature, pressure, any co-catalyst used etc.) or "tomato Extract" or "*Areola* extract". Steps preparation of "tomato extract" and "*Acerola*" extract has also not been described.

An artisan in the art would not be able to practice the invention because an undue experimentation without reasonable expectation of success will be required to prepare "cartilage enzymatic hydrolysate", or "tomato Extract" or "*Acerola* extract" other than the "grape seed extract" according to the recitation in instantly claimed invention. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Second Paragraph Rejections

11. In response to rejections to Claims 65-69, 71, 73-76 and 78-91 under the 35 U.S.C. §112, second paragraph in the Office Action mailed 05 May 2004, applicant argues that applicant has deleted the term "cartilage extract" or "tomato extract" or other indefinite verbiage in Claim 65 and those dependent on Claim 65. "Accordingly, the rejection of Claims 66-69, 73, 75-76, 79, 82-83, 85 and 90-91 which directly or indirectly depend from Claim 65 and also do not contain the terms "cartilage extract" or "tomato extract" has been rendered moot".

Applicant's arguments filed 05 November 2004 in regard to rejections made under the 35 U.S.C. §112, second paragraph in the Office Action mailed 05 November 2004 have been fully and carefully considered, but they are not persuasive. The rejections under 35 U.S.C. § 112, second paragraph to Claims 65 and those dependent on said Claim (e.g., 74) and 85-86 are adhered to for the reasons of record, and because Claims 74 and 85-86 still recite the word "extract".

12. In view of applicant's amendment filed 05 November 2004, following is a new rejection under 35 U.S.C. §112, second paragraph to Claims 69, 71, 73-76 and 78-91 and newly presented Claims 92-103 that are dependent directly or indirectly on Claim 65.

13. Claims 65-69, 73-76 and 79, 82-87, 90-91 and newly presented Claims 92-103 dependent directly or indirectly on Claim 65 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- As currently presented, Claims 65-69, 73-76 and 79, 82-87, 90-91 and newly presented Claims 92-103 are very confusing and unclear. For e.g., from their presentation in current form, Claims 65, 68, 71, 73, 74, 76, 78 and 80-90 do not clarify:
    - Whether applicant's claimed composition is comprised of chemicals/ingredients obtained from natural or synthetic sources or what is the real source for the components comprising applicant's claimed composition?
    - Whether the composition is comprised of cartilage enzymatic hydrolysate, grape seed extract, plant extract, tomato extract or of the components/chemical compounds that may be present in extracts obtained from those sources in a particular method, wherein each and every step, including a recovery step for a particular chemical compound/component is clearly delineated,
    - Applicant needs to clearly state the claimed composition in an independent claim/claims and in subsequent/, dependent claims indicate same component/chemical compound. E.g., if lycopene, rather than tomato extract is the lipophilic antioxidant component comprising applicant's claimed composition, applicant should state lycopene in subsequent/dependent claims rather interchangeably using lycopene and tomato extract. This is because tomato extract, depending on the steps of preparing said extract and solvents utilized to prepare said extract would have a composition entirely different than that of a composition comprising lycopene alone. Same criteria apply for cartilage enzymatic hydrolysate, grape seed extract, plant extract and any other extract that the applicant is claiming as a component for the claimed composition.
- Examiner suggests that applicant should rewrite Claims cited *supra* along the Examiner's suggestion stated *supra.* In rewriting, said Claims, however, applicant should ensure that no new matter is added.
- Claims 74 and 85-86 are rendered vague and indefinite by the term "extract" in those Claims because in those Claims, this term, in and of itself, does not adequately delineate its metes and bounds. For example, is said extract obtained by extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? Furthermore, in claims where tomato/ cartilage or fish extract is recited, the plant/ animal part (e.g., tomato seed or fruit/ fish bone or cartilage) should also be clearly specified because for e. g., it is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants/herbs, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein. Since the extract/extracts themselves are clearly essential to the claimed invention, the steps(s) by which the claimed extract/ extracts are obtained are also clearly essential and, therefore, must be recited in the claim language itself. Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

- Examiner suggests as a guidance that Applicant should for e.g., define the terms: "cartilage hydrolysate", "tomato extract" and "*Acerola* extract" etc. with the same/similar verbiage as has been used to define the "grape seed extract" at Page 8, Lines 24-31 of the specification and in Claims 92, 102 and 103.

- In Claim 75, "xanthofyll" is still misspelled. Appropriate correction (i.e., xanthophyll) is required.

- The phrase, " form suitable for oral administration" in claim 91 is unclear, vague, confusing and indefinite. It is not clear how one can determine with clarity and accuracy what form of a composition is suitable (i. e., capsule, concoction, elixir, powder, syrup or tablet), and what may be a suitable form for one may not be suitable for another. Applicant is advised to define the phrase " form suitable for oral administration".

All other claims depend directly or indirectly from the rejected claim (65) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections Under 35 U.S.C. § 102

14. In response to art rejections to Claims 65-69, 73-75 and 78 under 35 U.S.C. §102(b) as anticipated by Greenberg (U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402) in Office Action mailed 05 May 2004, applicant argues that "Office Action has not established that Greenberg inherently anticipates the claims of the instant invention" because "Greenberg's and Bombardelli et al's exhaustive list of components comprising the composition that Greenberg teaches does not comprise glycosaminoglycan, polyphenolic, hydrophilic antioxidants and lycopene (See applicant's Remarks Page 12, Lines 16). Citing MPEP, Applicant further argues that "it is not the case that Greenberg "inherently comprises both antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line 37) and beta carotene (i.e., β-carotene)", "the Office Action has not shown that lycopene is "necessarily present" in a composition described in Greenberg".

Applicant's arguments have been fully and carefully considered but are not persuasive for the reasons of record on Page 6, item 11 of Office action cited *supra* and for the reasons discussed *infra*. Since the Examiner-cited reference teaches a composition comprising cartilage extract, hydrophilic antioxidants, lycopene and β-carotene (see Column 2, Line 63), said β-carotene being an antioxidant according to applicant's own assertion, Greenberg's composition teaches a composition comprising a mucopolysaccharides (i.e., glycosaminoglycan, See Stedman's Medical Dictionary), polyphenolic, hydrophilic antioxidants and lycopene (See Column 3, Line 36 after the word "trypsin") because said

cartilage extract would inherently comprise glycosaminoglycan=mucopolysaccharides. As discussed *supra*, Greenberg's composition inherently comprises both antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line37) and beta- carotene (i.e., β-carotene).

Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility.** (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can,* state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

With reference to anticipation rejections cited *supra*, the first of Feit et al's teachings is met because Greenberg (U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402) teaches a composition comprised of same ingredients as claimed instantly. The second and third teachings from Feit et al., logically follow because the first teaching is met from teachings described in the cited prior art reference, i.e., Greenberg with evidence provided by Bombardelli et al.

Claim Rejections Under 35 U.S.C. § 103(a)

15. In view of applicant's amendment filed 05 November 2004, following is a new rejection under 35 U.S.C. §103(a) to Claims 65-69, 71, 73-76 and 78-91 and newly presented Claims 92-103 that are dependent directly or indirectly on Claim 65.

16. Claims 65-69, 71, 73-76 and 78-91 and newly presented Claims 92-103 that are dependent directly or indirectly on Claim 65 are rejected under 35 U.S.C. § 103 (a) as being obvious/unpatentable over Greenberg (U.S. Patent 5,569,458) in view of Spraycar (, M. (editor). Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 121, Column 1, Lines 44-48), Bombardelli et al. (EP 0,6559,402) and Kosbab (WO 00/07607) and further in view of Hersh (U.S. Patent 5,906,811) and Murad (U.S. Patent 6,630,163) for the reasons of record at pages 7-10 (See items 13 and 14) in Office Action mailed May 05, 2004 and for additional reasons as discussed *infra*.

Claims recite a composition comprising cartilage enzymatic hydrolysate or a compound (i.e., glycosaminoglycan) obtained from cartilage enzymatic hydrolysate, hydrophilic antioxidants and licopene,

wherein said hydrophilic antioxidants are obtained from a synthetic or natural source. Said natural source are plant extract components, more specifically oligomeric procyanidol from grape seed extract, lycopene and carotenes. The source for said plant extracts are anyone of following plants: *Aesculus hippocastanum*, *Ginkgo biloba*, pine bark, *Silybum marianum*, tomato, *Vaccinium myrtilius* and *Vitis vinifera*.

Teachings from each one of Greenberg, Spraycar, Bombardelli et al., Kosbab, Hersh and Murad have already been discussed at pages 7-10 in Office Action mailed May 05, 2004. In the citation referred to *supra*, the reasons for combining the beneficial teachings from each one of Spraycar, Bombardelli et al., Kosbab, Hersh and Murad how each one of the above cited references remedy the deficiencies in Greenberg's teachings have also been discussed. Furthermore, why those teachings in combination teach a composition comprising cartilage enzymatic hydrolysate or a compound (i.e., glycosaminoglycan) obtained from cartilage enzymatic hydrolysate, hydrophilic antioxidants and licopene as claimed in the instantly claimed invention is also discussed (See, Pages 7-10, more specifically items 13 and 14 in Office Action mailed May 05, 2004).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and for the following reasons. No patentable weight is given This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism without any criticality to the proportions or relative amounts or unexpected results is seen in a combination of a composition; or an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 7-10 (See items 13 and 14) in Office Action mailed May 05, 2004 and for additional reasons as discussed in item 16, Lines8-17 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

CONCLUSION

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. For the aforementioned reasons, no claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 8:15 A.M. to 6:45 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

January 24, 2005

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200